REMARKS

Claims 35-41 are pending in the application.

Claims 35-41 were previously added.

Claims 1-34 were previously cancelled.

The currently pending claims are recited in Applicants' previously submitted Amendment and Reply Under 37 C.F.R. § 1.111 and Supplemental Information Disclosure Statement, Paper No. 8, dated September 29, 2003, which is hereby incorporated herein by reference. Applicants' instant paper does not amend the claims.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 35-38 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly "failing to comply with the written description requirement." The Examiner alleged, "There does not appear to be any evidence disclosed in the specification of synergism between gabapentin and NMDA receptor antagonist. Nor is there a disclosure of the ratio of 1:50 to 50:1." Applicants respectfully disagree. The instant specification provides support for synergism and for the ratios.

Support for synergism of pain alleviating effects for combinations of gabapentin or pregabalin and an NMDA receptor antagonist is found in the instant specification on page 2, at lines 15-18, wherein the pain relief provided thereby is characterized as "unexpected" and "improved". This characterization denotes synergistic activity of all combinations of the present invention.

Support for the weight/weight ratio of from 1:50 to 50:1 is found in instant Example 1 and the support in the instant specification on page 12, at lines 16-19. The limitations of instant Example 1 may be optionally applied to any or all invention combinations. Accordingly, the teaching of instant Example 1 supports the limitation of the weight/weight ratio of from 1:50 to 50:1 of the instant claimed combinations.

Accordingly, Applicants deem that the synergism and ratio limitations of instant Claims 35-38 do not constitute new matter, and that Claims 35-38 thus comply with the written description requirement of 35 U.S.C. § 112.

In view of the above remarks, Applicants believe that the rejection of Claims 35-38 under 35 U.S.C. § 112, first paragraph, is overcome and request withdrawal of the rejection.

Claim Rejections - 35 U.S.C. § 102

Claims 35-41 are rejected under 35 U.S.C. § 102(e) as allegedly "being anticipated by Caruso et al US 6,187,338 B1." The Examiner alleged, "Claim 2 shows a combination of gabapentin and an NMDA receptor antagonist. Claim 8 clearly shows methods for treating pain. Particular anticonvulsants in addition to gabapentin which include pregabalin are shown in column 2, lines 29-34." Applicants respectfully disagree. Caruso et al. does not show pregabalin and does not anticipate the instant claims.

Caruso et al. discloses in Claim 2, "A therapeutic composition comprising (a) a neuropathic pain-alleviating amount of gabapentin anticonvulsant and (b) an anticonvulsant-potentiating amount of at least one nontoxic antagonist for the NMDA receptor or nontoxic substance that blocks a major intracellular consequence of NMDA receptor activation." In Claims 1 and 2 of Caruso et al., the "at least one" phrases describe a large number of possible compounds that are nontoxic antagonists for the NMDA receptor or nontoxic substances that blocks a major intracellular consequence of NMDA receptor activation". Also, Claims 1 and 2 of Caruso et al. embrace an infinite number of ratios of the anticonvulsant component to any one of the NMDA-active component(s), including ratios that are greater than 50:1 or less than 1:50, respectively.

For proper anticipation, all of the elements of the claimed invention must be found within the four corners of a single reference. Caruso et al. does not disclose the instant weight/weight ratios. Accordingly, Caruso et al. <u>does not anticipate</u> the invention combinations of instant Claims 35 or 36.

Also, Applicants respectfully point out that column 2, at lines 29-34, of Caruso et al. does not disclose pregabalin *per se* as the Examiner alleged, because to the best of Applicants' knowledge the publication dates (1990 and 1985) of the references cited in column 2, at lines 29-34, of Caruso et al. predate public disclosure of pregabalin *per se*.

In view of the above remarks, Caruso et al. does not anticipate the invention combinations of instant Claims 35 and 36, and Claims 35 and 36 are thus patentable under 35 U.S.C. § 102(e).

If the instant claimed combinations are not anticipated by Caruso et al., then the instant claimed pharmaceutical compositions of Claims 37 and 38 comprising the combinations and the instant claimed methods of Claims 39 to 41 of treating using the pharmaceutical compositions are not anticipated by Caruso et al. and are also patentable under 35 U.S.C. § 102(e).

In view of the above remarks, Applicants believe that the rejection of Claims 35-41 under 35 U.S.C. § 102(e) is overcome and request withdrawal of the rejection.

Supplemental Information Disclosure Statement

Applicants herein make available to the Patent and Trademark Office United States Patent Numbers 4,024,175; 4,087,544; 5,563,175; 6,001,876; and 6,197,819, and PCT International Patent Application Publication Number WO 93/23383, which are cited by Applicants in the enclosed Supplemental Information Disclosure Statement.

The Examiner is respectfully requested to consider carefully the complete text of the cited reference in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a).